AARP
Real Possibilities

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House Insurance Committee
via email to Committee Clerk Sergio Cavazos at Sergio.Cavazos_HC@house.texas.gov

Interim Charge #1: HB 2536

The passage of HB 2536 brought welcome transparency for Texas patients and employers struggling with the rising price of prescription drugs. Early evidence from the new law indicates that much more needs to be done and the state should look at improvements to the reporting requirements of the law as pharmaceutical manufacturers are largely not following the intent of the law in explaining the factors that specifically contributed to price increases. The state should also consider further action to protect patients from the uninhibited growth in prescription drug prices. Of particular concern for consumers is the rise in prices for insulin and supplies required for Texans living with diabetes. Several states now have taken action to protect consumers and Texas should consider steps that would get to the root of the problem – manufacturers raising prices at outrageous rates for medications that have been on the market for decades.

Improving on HB 2536

The much anticipated pharmaceutical manufacturer price increase reports became publicly available at TexasRx.org in late August of 2020 and though the information provided is limited - and drug manufacturers are not meeting the requirement to explain the factors associated with the price increases - the reports signal major issues worth investigation and continued focus by the legislature. As of August 24, 2020 there were 110 filed reports including these highlights:

One company, Otsuka America Pharmaceutical, Inc., claimed in all of their price increase reports that "pricing plans are proprietary and Otsuka does not believe this information is in the public domain or otherwise publicly available". Importantly, transparency alone is not actually a victory for consumers but Otsuka isn't even complying with this portion of the law. If companies like Otsuka want to reject transparency aimed at pressuring companies to be responsible to consumer concerns, then Texas leaders may want to consider stronger proposals (described below) to aim more directly at the problem of out of control drug prices. Furthermore, the Health & Human Services Commission (HHSC) should challenge this assertion and demand that the information be made public as required by HB 2536.

HB 2536 requires that pharmaceutical manufacturers provide "a statement regarding the factor or factors that caused the increase in the wholesale acquisition cost and an explanation of the role of each factor's impact on the cost." Companies are boldly ignoring this legislative mandate in their price increase reports. Here are just a few examples of the meaningless statements drug manufacturers are making that do not meet the intent of the new law:

- ACADIA Pharmaceuticals – "ACADIA prices our medicines to reflect their value to patients, payers and society. Our goals are to reduce the burden of disease and deliver better health outcomes with our therapies."
- Neos Therapeutics, Inc. – "Increased manufacturing costs; Increased costs from operations; Increased distribution costs; Increase payer rebate costs"
- Currax Pharmaceuticals LLC – "Distribution costs - continued inflationary costs of wholesaler distribution; Discounts or Rebates - increased administration costs of rebate programs"

The House passed version of HB 2536 required that manufacturers list "all factors that caused the increase in the wholesale acquisition cost" and "the percentage of the total increase in the wholesale acquisition cost that is attributable to each factor". This important provision was removed before final of the bill and would be a useful tool to help consumers understand the actual impact that various factors contribute to the total price increase.

Strengthen Consumer Protections

Further research into the price reports unveil some concerning trends. The reports allow us to see how pharmaceutical manufacturer business strategy trends impact consumers directly. Take for example Zyla Life Sciences (formerly Eglat). The company announced the "closed restructuring transaction and acquisition of five new products" per their 1st quarter 2019 SEC filing. Two of those products showed up in price increase reports required under HB 2536 and it was all bad news for consumers.

1 year price increase for Zorvolex (diclofenac): anti-inflammatory/pain reliever

Effective Date	Product	Lowest WAC	1-yr $ Increase	New WAC	% Increase
1/1/2020	Zorvolex	$383.05	$331.30	$714.35	86%

3 year price increase for Zorvolex (diclofenac): anti-inflammatory/pain reliever

Effective Date	Product	Lowest WAC	3-yr $ Increase	New WAC	% Increase
1/1/2020	Zorvolex	$318.60	$395.75	$714.35	124%

1 year price increase for Indocin (indomethacin): anti-inflammatory/pain reliever

Effective Date	Product	Lowest WAC	1-yr $ Increase	New WAC	% Increase
1/1/2020	Indocin	$2550	$3054.9	$5604.9	120%

3 year price increase for Indocin (indomethacin): anti-inflammatory/pain reliever

Effective Date	Product	Lowest WAC	3-yr $ Increase	New WAC	% Increase
1/1/2020	Indocin	$690.30	$4914.60	$5604.90	712%

Pharmaceutical manufacturers routinely point out that the wholesale acquisition cost (WAC) is not the cost that the end user sees and negotiations with pharmacy benefit managers and government payers result in price reductions. However, when we see the base price of a drug increase by 712% percent in just three years following an acquisition from another company, there is clear indication of a market failure for patients that need this medication. There are numerous other stories that can be extrapolated from the price increase report, Zyla's price increases are just one set of examples. However, the transparency here is incomplete. Zyla's explanation of the increase offered meaningless transparency about why they increased the price of the drug and even cited illogical arguments about "generic competition" and "competitive influences".

Focus on Protecting Patients Struggling with High Insulin Costs

While pharmaceutical manufacturers routinely point to their own patient assistance programs as the answer to affordability concerns following outrageous price increase for insulin, the reality is that rationing is still a common practice. These assistance programs, often limited to only uninsured patients - are clearly missing the masses of Americans with diabetes struggling to stay healthy. A team of Yale researchers found that one in four patients at an urban clinic were rationing insulin for affordability reasons. These rates of rationing were echoed in an in an international study that found that US rates (26%) far exceeded international rates of (18%). The problem is fortunately fairly simple as one researcher describes:

> *"Back in 1996, when Eli Lilly's Humalog first came out, the price for a 1-month supply of insulin was $21. As of 2001, that exact vial's price increased by $14 to $35. Now, in 2019, that vial is said to be around $275. That is a 1200% increase on the original price."*

The Texas Legislature should consider proposals that reach the root of the problem – outrageous price hikes. Out-of-pocket caps can be a useful tool in limiting immediate exposure to rampant price hikes of insulin, however, these proposals do not put pressure on manufacturers to control prices and ultimately the cost of associated with capping out-of-pocket expenses is shifted to premiums paid by insured Texans and their employers.

Recommendations:

- Require manufacturers to detail specific factors and the portion of the price increase related to that factor as was required in the House passed version of HB 2536.
- Require further detail in explaining price increases including specifics information on the drug's acquisition (if applicable) and specific cost attributed to the drug. See the National Academy of State Health Policy model bill for further detail.
- Consider various state proposals to create pressure on drug manufacturers to control price increases and protect state budgets including: create price gouging protections with Attorney General enforcement, use an international reference price for state funded health plans to set an upper payment limit for certain drugs for state purchasers, importation of lower costs drugs, and other proposals.
- Create an insulin safety net program funded by insulin manufacturers to ensure no Texan suffers the negative health effects of rationing insulin. Minnesota's new law creates a largely industry funded safety net programs that helps both uninsured patients and those patients with insurance and high out-of-pocket costs.

Sincerely,

M. Blake Hutson

Blake Hutson
AARP Texas